



CYBER LETTER

April 5, 2010

Mr. Ricardo Rego
Zipmed.net
Mesoone.com
Rua Erico Mota 1149A
Fortaleza, CE 60455600
Brazil

Dear Mr. Rego:

The United States Food and Drug Administration (FDA) has reviewed your websites, www.zipmed.net and www.mesoone.com, and has determined that you promote and sell lipodissolve and mesotherapy products containing phosphatidylcholine and deoxycholate (PCDC) including, but not limited to, PCDC German Phosphatidylcholine, New German Phosphatidylcholine PCDC, PCDC German Phosphatidylcholine Professional Lipodissolve, Deoxycholate 6%, and Kit Deoxycholate 6% Cellulite and Love Handles. These products are intended to cure, mitigate, treat, or prevent disease in humans, or to affect the structure or function of the body. Statements on your websites that document these intended uses include, but are not limited to, the following:

- “Lipo dissolve will dissolve fat permanently in the area of treatment, leaving only a thin layer of cells.”
- “Lipodissolve treatment is a pharmaceutical compound called phosphatidylcholine deoxycholate, or PCDC, which is administered through a series of micro-injections to permanently dissolve the fat.”
- “To dissolve these pockets of fat, PCDC micro-injections are delivered into the targeted treatment areas. The fat cells absorb the PCDC and become slightly inflamed, then harden. The hardened fat cells break down within a few weeks leading to measurable inch loss. At this point, the fat cell no longer exists and has been permanently removed from the body.”
- “Deoxycholate works as detergents do, causing the oily cell wall and other fats to be dissolved in the watery fluid around the fat cells.”
- “For some years now, phosphatidylcholine has also been used for subcutaneous treatments of circumscribed fat deposits at eyelids, abdominal folds, flanks, upper and lower limbs and other body areas; and the clinical results have been excellent.”

- “We’ve seen tremendous results with men who have gynecomastia [*sic*], or enlarged breasts.”

Because these products are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans, or to affect the structure or any function of the body of man or other animals, they are drugs, as defined by section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(g)(1). Moreover, these products are new drugs, as defined by section 201(p) of the Act, 21 U.S.C. § 321(p), because they are not generally recognized as safe and effective for use under the conditions prescribed, recommended, or suggested in their labeling. Under sections 301(d) and 505(a) of the Act, 21 U.S.C. §§ 331(d) and 355(a), a new drug may not be introduced or delivered for introduction into interstate commerce unless an FDA-approved application is in effect for it. Your sale of these products to consumers in the United States without an approved application violates these provisions of the Act.

In addition, your firm’s injectable lipodissolve products are misbranded under section 503(b)(1) of the Act, 21 U.S.C. § 353(b)(1), because the method of their use is not safe for use except under the supervision of a practitioner licensed by law to administer such drugs. Therefore, these injectable products may be dispensed only upon prescription of a licensed practitioner. Because you dispense these products without such a prescription they are misbranded under section 503(b)(1) of the Act (21 U.S.C. § 353(b)(1)). These products are also misbranded under Section 503(b)(4)(A) of the Act (21 U.S.C. § 353(b)(4)(A)) in that their labels fail to bear, at a minimum, the symbol “Rx only.” Your marketing of these misbranded products to consumers in the United States violates Section 301(a) of the Act (21 U.S.C. § 331(a)).

Furthermore, because these products are offered for conditions, such as gynecomastia, that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners, adequate directions cannot be written so that a layman can use them safely for their intended uses. Thus, your firm’s drug products fail to bear adequate directions for their intended uses, causing them to be misbranded under section 502(f)(1) of the Act, 21 U.S.C. § 352(f)(1). Therefore, the introduction or delivery for introduction into interstate commerce of these products violates section 301(a) and (d) of the Act, 21 U.S.C. §§ 331(a) and (d).

The above violations are not intended to be an all-inclusive list of deficiencies. It is your responsibility to ensure that all of the drug products marketed to individuals in the U.S. by your firm are in compliance with United States laws. We advise you to review your websites, products, product labels, and other labeling and promotional materials for your products to ensure that your products conform to provisions of the Act and FDA requirements.

With a copy of this letter, we are advising the drug regulatory officials in Brazil of these potential violations. In addition, we have advised the FDA field personnel and the public through an Import Alert that all shipments of your products offered for importation into the United States may be detained and subject to refusal of entry.

A description of the new drug approval process can be found on FDA’s internet website at <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm090361.htm>. If you need

additional information or have questions concerning the marketing and distribution of your products within the United States, please contact the FDA. Any correspondence should be directed to the Food and Drug Administration, Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, 10903 New Hampshire Avenue, WO51-2201, Silver Spring, MD 20993-0002, USA.

You may also provide a written response to this letter via fax to Sudha Shukla at (301) 847-8745.

Sincerely,



/Michael M. Levy, Jr./

Michael M. Levy, Jr., Director
Division of New Drugs and Labeling Compliance
Center for Drugs Evaluation and Research
Office of Compliance

Cc:

Dr. Dirceu Raposo de Mello
Diretor-Presidente
Agência Nacional de Vigilância Sanitária (ANVISA)
SIA, Trecho 5, Área Especial 57
Brasília – DF, Brazil
CEP: 71.205-050

MESOONE.COM LTD
315 Seaview Avenue
#12080
Bridgeport, Connecticut, 06607-2433